## DETAILED ACTION

1. Applicant's amendments filed on 11/12/2009 and 02/10/2010 are acknowledged.

2. Claims 19, 39-40, 45-48 and 53 are pending.

3. In view of the amendments filed on 11/12/2009 and 02/10/2010, claims 19, 45, 48 and 53 are now directed to allowable products. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 39-40 and 46-47 directed to processes of using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 03/19/2008 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Page one, line one of the specification should be updated to reflect the status of related applications.

***Specification***

5. The specification is objected to because of the following informalities:

All sequences listed in Figures 2-4 must be identified in the Brief Description of the Drawings.

Correction is required.

6. The abstract of the disclosure is objected to because it was not submitted on a separate sheet of paper. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure:

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It

should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The following new grounds of rejection are necessitated by Applicant's amendments filed on 11/12/2009 and 02/10/2009.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 47 recites the limitation "said condition" in line 1. There is insufficient antecedent basis for this limitation in the claim since the amendment to claim 46 filed on 02/10/2010 deleted the term "condition" in claim 46.

Correction is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 46-47 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method of detecting hypersensitivity to a grass pollen of the subfamily Pooideae in a mammal, comprising measuring Lol p 5 T cell proliferation and IL-5 and IFN-γ production induced by the peptides of SEQ ID NOs 33, 45, 46 and 53-54 wherein an

increase in T cell proliferation and IL-5 and IFN-γ production indicates the presence of hypersensitivity to said grass pollen, does not provide reasonable enablement for: a method of **diagnosing or monitoring a hypersensitivity** to a grass pollen of the subfamily Pooideae in a mammal said method comprising the steps of (a) obtaining **cells derived from the peripheral blood or from tissue biopsies of the mammal**, (b) combining the cells with the peptides according to claim 19, and (c) measuring **the activity** of the cells before and after step (b), wherein an increase in **activity indicates the presence or increase of hypersensitivity to grass pollen** of claim 46; and wherein said condition is hypersensitivity to Rye grass or Timothy grass pollen of claim 47. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification discloses on pages 52-57 that T cell proliferation and IL-5 and IFN-γ production induced by the peptides of SEQ ID NOs 33, 45, 46 and 53-54 indicates the presence of hypersensitivity to said grass pollen.

The specification does not adequately disclose that any T cell activity induced by the peptides SEQ ID NOs 33, 45, 46 or 53-54 can be used to diagnose or monitor hypersensitivity to grass pollen of the subfamily Pooidae. The art of Burton et al. teaches that SEQ ID NOs 33, 45, 46 and 53-54 induce Lol p 5 reactive T cells to proliferate and produce IL-5 and IFN-γ (In particular, 'Results' section of abstract, Table 2, Figure 3, whole document). Burton et al. shows that one cannot measure any activity of T cells to determine hypersensitivity since Lol p 5 hypersensitivity was associated with a specific set of activities, namely T cell proliferation and production of IL-5 and IFN-γ. As such, one of ordinary skill in the art would be required to perform undue experimentation to determine which of all T cell activities are indicative of hypersensitivity.

The specification has also not adequately disclosed a method where any activity induced by any cells isolated from peripheral blood or tissue can be measured to indicate Lol p 5 hypersensitivity. The specification discloses a method of measuring the proliferative response of T cells isolated from the peripheral blood. But, the specification does not adequately disclose how any cell may be adequately used in the instant method without undue experimentation by one or ordinary skill in the art. As recited, the claims encompass the use of measuring any activity in any cell type from any tissue to determine hypersensitivity. One of ordinary skill in

the art would be required to perform undue experimentation to practice the invention commensurate in scope with the claims.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. Claims 46-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: a method of detecting hypersensitivity to a grass pollen of the subfamily Pooideae in a mammal, comprising measuring Lol p 5 reactive T cell proliferation and IL-5 and IFN-γ production induced by the peptides of SEQ ID NOs 33, 45, 46 and 53-54 wherein an increase in T cell proliferation and IL-5 and IFN-γ production indicates the presence of hypersensitivity to said grass pollen.

Applicant is not in possession of: a method of diagnosing or monitoring a hypersensitivity to a grass pollen of the subfamily Pooideae in a mammal said method comprising the steps of (a) obtaining **cells derived from the peripheral blood or from tissue biopsies of the mammal**, (b) combining the cells with the peptides according to claim 19, and

(c) measuring **the activity** of the cells before and after step (b), wherein an increase in **activity** indicates the presence or increase of hypersensitivity to grass pollen; and wherein said condition is hypersensitivity to Rye grass or Timothy grass pollen of claim 47.

Applicant has disclosed only a method of detecting hypersensitivity to a grass pollen of the subfamily Pooideae in a mammal, comprising measuring Lol p 5 reactive T cell proliferation and IL-5 and IFN-γ production induced by the peptides of SEQ ID NOs 33, 45, 46 and 53-54 wherein an increase in T cell proliferation and IL-5 and IFN-γ production indicates the presence of hypersensitivity to said grass pollen; therefore, the skilled artisan cannot envision all the contemplated cell, tissue, activity and method possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

13. Claims 19, 39-40, 45, 48 and 53 are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 23, 2010

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644